



Patent  
Attorney's Docket No. 032775-078  
attached

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of )

Coffey et al. )

Application No.: 09/987,687 )

Filed: November 15, 2001 )

For: METHOD FOR OPTIMALLY )  
DELIVERING VIRUS TO A SOLID )  
TUMOR MASS )

Group Art Unit: 1614

Examiner: Unassigned

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**INFORMATION DISCLOSURE STATEMENT  
TRANSMITTAL LETTER**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.


- ☒ No additional fee for submission of an IDS is required.
- ☐ The fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A certification under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A certification under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge \$\_\_\_\_\_ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of \$\_\_\_\_\_ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(650) 622-2300

By:   
Ping F. Hwung  
Registration No. 44,164

Date: January 22, 2002



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**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56,  
Applicants hereby submit the following information in conformance with 37 C.F.R.  
§§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is  
enclosed.

**United States Patents**

	<u>Inventor</u>	<u>Issue date</u>	<u>Patent No.</u>
1.	Lee et al.	August 29, 2000	6,110,461
2.	Lee et al.	October 24, 2000	6,136,307

**Foreign Patents**

3.	WO 94/18992	Published September 1, 1994
4.	WO 94/25627	Published November 10, 1994
5.	WO 99/08692	Published February 25, 1999

**Articles**

6. Bar-Eli, N., et al., "preferential cytotoxic effect of Newcastle disease virus on lymphoma cells", *J. Cancer Res. Clin. Oncol.* **122**: 409-415 (1996).
7. Bischoff JR. et al., "An Adenovirus Mutant that Replicates Selectively in p53-Deficient Human Tumor", *Science* **274(5286)**:373-6 (1996).
8. Blagoslelonny, M.V., et al., "*in vitro* Evaluation of a p53-Expressing Adenovirus as an Anti-Cancer Drug", *Int. J. Cancer* **67(3)**:386-392 (1996).
9. Brooks et al., eds. "Jawetz, Melnick, & Adelberg's Medical Microbiology" (1998).
10. Chandron and Nibert, "Protease cleavage of reovirus capsid protein mu1 and mu1C is blocked by alkyl sulfate detergents, yielding a new type of infectious subviriion particle", *J. of Virology* **72(1)**:467-75 (1998).
11. Chang et al., *J. Virol.* **69**:6605-6608 (1995).
12. Chang et al., *Virol.* **194**:537-547 (1993).
13. Chang et al., *Proc. Natl. Acad. Sci.* **89**:4825-4829 (1992).
14. Coffey, M.C., et al., "Reovirus therapy of tumors with activated Ras pathway", *Science* **282**: 1332-1334 (1998).
15. Fueyo, J., et al., "A Mutant Oncolytic Adenovirus Targeting the Rb Pathway Produces Anti-Glioma Effect *in Vivo*", *Oncogene* **19(1)**:2-12 (2000).
16. Haig, D.M. et al., *Immunology* **93**:335-340 (1998).
17. He, B. et al, *Proc. Natl. Acad. Sci.* **94**:843-848 (1997).
18. Heise, C. et al., "Replication-selective adenoviruses as oncolytic agents", *J. Clin. Invest.* **105(7)**:847-51 (2000).
19. Kawagishi-Kobayashi, M. et al., *Mol. Cell. Biol.* **17**:4146-4158 (1997).
20. Nemunaitis, J., *Invest. New Drugs* **17**:375-386 (1999).

21. Reichard, K.W., et al., "Newcastle Disease Virus Selectively Kills Human Tumor Cells", *J. of Surgical Research* **52**:448-453 (1992).
22. Romano et al., *Mol. Cell. Bio.* **18(12)**:7304-7316 (1998).
23. Sharp et al., *Viol.* **250**:302-315 (1998).
24. Stojdl, D.F., et al., "Exploiting Tumor-Specific Defects in the Interferon Pathway with a Previously Unknown Oncolytic Virus", *Nat. Med.* **6(7)**:821-825 (2000).
25. Strong, J.E. and P.W. Lee, "The v-erbV oncogene confers enhanced cellular susceptibility to reovirus infection", *J. Virol.* **70**: 612-616 (1996).
26. Strong, J.E., et al., "Evidence that the Epidermal Growth Factor Receptor on Host Cells Confers Reovirus Infection Efficiency", *Virology* **197(1)**: 405-411 (1993).
27. Strong, J.E., et al., "The molecular basis of viral oncolysis: usurpation of the Ras signaling pathway by reovirus", *EMBO J.* **17**: 3351-3362 (1998).
28. Yoon, S.S., et al., "An Oncolytic Herpes Simplex Virus Type I Selectively Destroys Diffuse Liver Metastases from Colon Carcinoma", *FASEB J.* **14**:301-311(2000).
29. Zorn, U. et al., "Induction of Cytokines and Cytotoxicity against Tumor Cells by Newcastle Disease Virus", *Cancer Biotherapy* **9(3)**:22-235 (1994).

These documents are being submitted within three months of the filing date of the present application. Consequently, no fee is required pursuant to 37 C.F.R. §1.97(b).


By citing the above references, Applicants do not acquiesce or admit that any of these documents are "prior art" under 35 U.S.C. Applicants specifically reserve the right, where appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: \_\_\_\_\_

  
Ping F. Hwang  
Registration No. 44,164  
Attorney for Applicants  
Redwood Shores, CA Office  
(650)-622-2300

P.O. Box 1404  
Alexandria, Virginia 22313-1404

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